

R E M A R K S

In the Office Action dated January 18, 2007, claims 1, 2 and 21 were rejected under 35 U.S.C. §102(e) as being anticipated by Schnall et al. Claims 3-48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schnall et al in view of Bailey et al.

These rejections are respectfully traversed for the following reasons. In the method and apparatus disclosed and claimed by the present application, a localized temperature *change* is produced at a body part of a subject containing vessels in which a body fluid flows. The flow of the body fluid in the vessels in the body part after the temperature change is then measured, dependent on the temperature *change*.

No such method or apparatus is disclosed or suggested in the Schnall et al reference.

The Schnall et al reference, as is clear from the abstract thereof and numerous other passages throughout the reference, proceeds on a completely different measurement basis from that disclosed and claimed in the present application. In the Schnall et al reference, a vessel is occluded exclusively by the application of pressure thereto, such as at a finger or toe (digit) of the subject. The occluding pressure is maintained for a predetermined time period, and is then removed in order to restore arterial blood flow in the vessel. The digit is then monitored for changes in the arterial tone that exist before and after the application of the occluding pressure. The endothelial activity of the patient is then evaluated based on these detected changes in the arterial tone.

Therefore, there is no selective dilation or constriction that takes place in the Schnall et al reference, but only constriction, and moreover this is necessarily an occluding (i.e., vessel-closing) constriction. There is no disclosure in the Schnall et al reference that, if the applied pressure did not occlude the vessel, the measurement and evaluation procedure in the Schnall et al reference would even be applicable.

In the Schnall et al reference, the application of a temperature change for selectively dilating or constricting a vessel is nowhere suggested. The Examiner cited paragraph [0020] of the Schnall et al reference on this point, but this passage in the Schnall et al reference concerns only the determination of a comparison or reference value for the measurement values that are subsequently acquired in the manner described above. In order to determine such a comparison or reference value, the value of the maximum blood flow after a local heating of the finger or toe, or the minimal blood flow after a local cooling of the finger or toe, is determined. Consequently, in the Schnall et al reference there is no measurement of, and no need to obtain a measurement of, a *change* in the temperature. In the Schnall et al reference, only the blood flow *at* a specific temperature is determined, and this is all that is necessary to be determined in order to satisfy the needs in the Schnall et al evaluation.

This passage in the Schnall et al reference, therefore, does not disclose the generation of a “controlled temperature change” in a body part, as set forth in the independent claims of the present application, after which a measurement ensues “dependent on the temperature change.”

The further paragraphs in the Schnall et al reference cited by the Examiner (paragraphs [0088] and [0089]) simply repeat the determination of a comparison or reference value at a specific temperature, as expressly stated in the last sentence of paragraph [0089]. At all locations in these passages, only the determination of a “base line” is discussed.

In view of the non-disclosure in the Schnall et al reference of producing a controlled temperature change in a body part, and measuring body fluid flow in vessels in the body part after the temperature change, dependent on the temperature change, Applicants submit this is sufficient to overcome the anticipation rejection based on Schnall et al. Nevertheless, independent claims 1 and 30 have been amended to make clear that, if a constriction is produced by the aforementioned controlled temperature change, it is a non-occluding constriction. Applicants acknowledge that the term “non-occluding” is not used in the present specification, because there was no need to refer to the constriction as being non-occluding at the time the present application was written. Nevertheless, as can be seen from Figure 2, the fluid flow never falls to a value of zero, nor does the vessel diameter, thereby providing sufficient disclosure for the use of this limitation in the independent claims, as a further basis for distinguishing those claims over the disclosure of the Schnall et al reference.

For the above reasons, the Schnall et al reference does not disclose all of the elements of claims 1, 2 or 21, and therefore none of those is anticipated by Schnall et al.

The Bailey et al reference merely provides generalized teachings regarding the application of temperature to living bodies, or body parts, and is concerned only

with cryotherapy or heatable products such as heatable hues or heatable car seats. As such, Applicants submit that a person of ordinary skill in the field of designing and constructing devices for examining blood vessel responsiveness would have no reason whatsoever to consult a reference such as Bailey et al. Even if the Examiner's conclusions regarding the Bailey et al reference are correct, however, modification of the Schnall et al reference in accordance with those teachings of Bailey et al still would not result in a method or an apparatus as set forth in any of claims 3-48, for the reasons discussed above in connection with the Schnall et al reference.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

 (Reg. 28,982)

SCHIFF, HARDIN LLP
CUSTOMER NO. 26574
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Applicants.

CH11 4921895.1